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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/913,345

03/25/2002

Jan Gerrit Garssen

5034US

8607

7590

01/26/2007

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

01/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/913,345

Applicant(s)

GARSSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): see attached Detailed Action.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 20 and 21.
Claim(s) objected to: _____.
Claim(s) rejected: 1-7, 11-16.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 1 November 2006, is acknowledged. Claims 1, 16, and 21 have been amended.
2. Claims 1-7, 11-16, 20, and 21 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) is withdrawn in light of the amendment of the claim to recite specific sequences.
4. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is withdrawn.

Rejections Maintained

5. The rejection of claims 1-5, 11-13, and 15 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) is maintained for reasons of record.

Applicants argue that the amendment to claims 1 and 21 to recite determining with anti-PrP^{Sc} antibodies instances of increased antibody reactivity as a function of denaturation in guanidine thiocyanate or one or more chaotropic agents in the test set versus the control set should place the claims into allowance as being novel and non-obvious over the cited art.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in prior Office Actions. Claim 1 is a method for reducing false-positive test results when testing ≥ 1 sample for the presence/absence of an aberrant prion protein, wherein said method comprises splitting one sample into a test and control set; treating the test set with guanidine thiocyanate or ≥ 1 chaotropic agent; leaving the control set untreated with

Art Unit: 1645

guanidine thiocyanate or ≥ 1 chaotropic agent; mixing both the test and control sets with anti-PrP^{Sc} antibodies; and determining increased antibody activity in the test set versus the control set.

The procedures taught by Grathwohl et al do teach the claim requirements. A sample is taken (brain and spleen, page 206, section 2.2). Two sets of sample preparations are made (GdnSCN, 0-5M; SDS) from the same sample. ELISA procedures are performed and the results of the GdnScn versus SDS sets compared (sections 2.4, 3.1; Fig. 2).

6. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) is maintained for reasons of record.

Applicants argue that because independent claim 1 is nonobvious, the dependent claims 6 and 7 are nonobvious.

The examiner has considered applicants' argument, but does not find it persuasive. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) and dependent claims 6 and 7 remain rejected for the reasoning put forth in prior Office Actions.

7. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is maintained for reasons of record.

Conclusion

8. Claims 1-7 and 11-16 remain rejected. Claims 20 and 21 appear to be free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)


Art Unit: 1645

272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 22, 2007